General

Guideline Title

Clinical practice guideline: improving voice outcomes after thyroid surgery.

Bibliographic Source(s)

Chandrasekhar SS, Randolph GW, Seidman MD, Rosenfeld RM, Angelos P, Barkmeier-Kraemer J, Benninger MS, Blumin JH, Dennis G, Hanks J, Haymart MR, Kloos RT, Seals B, Schreibstein JM, Thomas MA, Waddington C, Warren B, Robertson PJ. Clinical practice guideline: improving voice outcomes after thyroid surgery. Otolaryngol Head Neck Surg. 2013 Jun;148(6 Suppl):S1-37. [256 references] PubMed

Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- December 14, 2016 – General anesthetic and sedation drugs : The U.S. Food and Drug Administration (FDA) is warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains. Consistent with animal studies, recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure affects children's brain development.

Recommendations

Major Recommendations

The evidence grades (A-D, X) and evidence-based statements (Strong Recommendation, Recommendation, Option, and No Recommendations) are defined at the end of the "Major Recommendations" field.

Statement 1. Baseline Voice Assessment

The surgeon should document assessment of the patient's voice once a decision has been made to proceed with thyroid surgery.

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C
- Benefit: Establish a baseline, improve the detection of preexisting voice impairment, establish expectations about voice outcomes, educating the patient, facilitates shared decision making, prioritize the need for preoperative laryngeal assessment and more in-depth voice assessment
- Risk, harm, cost: Anxiety, cost of assessment tool, patient and provider time
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Perception by the Guideline Development Group (GDG) of a current underassessment of voice prior to surgery
- Intentional vagueness: The proximity of the assessment to the day of surgery is not specified because there was no consensus among the guideline group and there were no data to support the choice of one time point over another. The group agreed that any change in voice would warrant a new assessment.
- Role of patient preferences: Selection of assessment methods
- Exclusions: None
- Policy level: Recommendation

Statement 2A. Preoperative Laryngeal Assessment of the Impaired Voice

The surgeon should examine vocal fold mobility, or refer the patient to a clinician who can examine vocal fold mobility, if the patient's voice is impaired (as determined by the assessment in Statement 1) and a decision has been made to proceed with thyroid surgery.

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C
- Benefit: Assess mobility of vocal fold, potential diagnosis of invasive thyroid cancer, influence the decision for surgery, extent of surgery, intraoperative technique, preoperative patient counseling, distinguish iatrogenic from disease related paralysis/paresis
- Risk, harm, cost: Misdiagnosis (false positive/false negative), cost of examination, patient discomfort, resources, access, anxiety
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Role of patient preferences: Limited
- Exclusions: None
- Policy level: Recommendation

Statement 2B. Preoperative Laryngeal Assessment of the Nonimpaired Voice

The surgeon should examine vocal fold mobility, or refer the patient to a clinician who can examine vocal fold mobility, if the patient's voice is normal and the patient has (a) thyroid cancer with suspected extrathyroidal extension, or (b) prior neck surgery that increases the risk of laryngeal nerve injury (carotid endarterectomy, anterior approach to the cervical spine, cervical esophagectomy, and prior thyroid or parathyroid surgery), or (c) both, once a decision has been made to proceed with thyroid surgery.

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C
- Benefit: Assess mobility of vocal fold, potential diagnosis of invasive thyroid cancer, influence the decision for surgery, extent of surgery, intraoperative technique, preoperative patient counseling, distinguish iatrogenic from disease related paralysis/paresis
- Risk, harm, cost: Misdiagnosis (false positive/false negative), cost of examination, patient discomfort, resources, access, anxiety
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Even though the prevalence of preoperative vocal fold paresis is low, the consequence of not knowing this prior to surgery could result in substantial morbidity or mortality. For this reason, the GDG was willing to accept a large number of normal examinations in return for an occasional abnormal finding.
- Intentional vagueness: The timing of assessment relative to surgery is not stated to allow clinicians flexibility in decision making, although the GDG agreed that the assessment should take place as close to the surgery as possible. The word suspected is used due to the difficulty of

identifying extrathyroidal extension through physical exam and imaging.
- Role of patient preferences: Limited
- Exclusions: None
- Policy level: Recommendation

Statement 3. Patient Education on Voice Outcomes

The clinician should educate the patient about the potential impact of thyroid surgery on voice once a decision has been made to proceed with thyroid surgery.

Recommendation based on preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade B, randomized controlled trials (RCTs) on the value of patient education in general regarding surgery; Grade C, studies on the incidence of voice impairment following thyroid surgery in particular
- Benefit: Facilitate shared decision making, establish realistic expectations, help patients recognize voice changes postoperatively
- Risk, harm, cost: Anxiety
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Generalize evidence about the benefits of patient education to this circumstance
- Intentional vagueness: None
- Role of patient preferences: Patient can decline information
- Exclusions: None
- Policy level: Recommendation

Statement 4. Communication With Anesthesiologist

The surgeon should inform the anesthesiologist of the results of abnormal preoperative laryngeal assessment in patients who have had laryngoscopy prior to thyroid surgery.

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C
- Benefit: Allow anesthesiologist to select proper tube, allow anesthesiologist to optimize airway management, identify potential problems with intubation and extubation, plan postoperative care and monitoring, may prevent anesthetic related voice disturbance
- Risk, harm, cost: None
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: The GDG felt that even though the recommendation followed best practice there was a perception the action was not universally performed.
- Intentional vagueness: Timing of discussion is not specified but should occur before the patient enters the operating room
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation

Statement 5. Identifying Recurrent Laryngeal Nerve (RLN)

The surgeon should identify the RLN(s) during thyroid surgery.

Strong recommendation based on a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade B, RCTs and retrospective cohort studies
- Benefit: Optimize voice outcome, protect the RLN, preserve laryngeal function, reduce incidence of RLN injury
- Risk, harm, cost: Inadvertent RLN injury, extended operative time, false identification of another structure as the RLN
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: None

- Role of patient preferences: None
- Exclusions: Thyroid surgery limited to the isthmus
- Policy level: Strong recommendation

Statement 6. Protection of Superior Laryngeal Nerve

The surgeon should take steps to preserve the external branch of the superior laryngeal nerve(s) when performing thyroid surgery.

Recommendation based on preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C
- Benefit: Preserves vocal projection and high frequencies
- Risk, harm, cost: May leave superior pole thyroid tissue
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: The steps taken to preserve the nerve are purposefully not specified in the statement to emphasize the important issue is preserving the nerve, which may or may not be identifiable during surgery. Therefore, it is the attention to the nerve that is important.
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation

Statement 7. Intraoperative Electromyography (EMG) Monitoring

The surgeon or their designee may monitor laryngeal EMG during thyroid surgery.

Option based on 1 RCT and observational studies with a balance of benefit versus harm.

Action Statement Profile

- Aggregate evidence quality: Grade C
- Benefit: Added information regarding neurophysiologic status of the RLN (specifically when the nerve is injured), potential improved accuracy in nerve identification, potentially avoiding transient/temporary nerve
- Risk, harm, cost: Cost of endotracheal tube and probe; capital equipment costs; education of key personnel including anesthesia, nursing, surgeon, and technician; misinterpretation (both false positive/false negative); may instill a false sense of security in identifying nerve
- Benefit-harm assessment: Equilibrium
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: None
- Policy level: Option

Statement 8. Intraoperative Corticosteroids

No recommendation can be made regarding the impact of a single intraoperative dose of intravenous corticosteroid on voice outcomes in patients undergoing thyroid surgery.

No recommendation based on observational studies with limitations and a balance of benefit versus harm.

Action Statement Profile

- Aggregate evidence quality: Grade D, observational studies with concerns over methodology and clinical importance
- Benefit: Uncertain effect on short-term voice improvement or shortening the duration of vocal fold paralysis or paresis.
- Risk, harm, cost: Hyperglycemia
- Benefit-harm assessment: Balance of benefit versus harm
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: None

- Exclusions: None
- Policy level: No recommendation

Statement 9. Postoperative Voice Assessment

The surgeon should document whether there has been a change in voice between 2 weeks and 2 months following thyroid surgery.

Recommendation based on systematic reviews, clinical practice guidelines, and prospective, observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C, cohort studies on the prevalence and duration of voice changes after thyroid surgery and the underreporting of voice changes if not specifically sought
- Benefit: Identification of significant voice impairment and early institution of counseling and/or voice rehabilitation; avoidance of patient anxiety
- Risk, harm, cost: Cost of assessment tools/examinations
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: The GDG believes that postoperative voice assessment is not being performed universally, in the identified time frame.
- Intentional vagueness: The documentation time is stated as between 2 weeks and 2 months because there is no evidence on the optimal time, but the GDG suggests that the evaluation should be late enough to overcome transient postoperative changes but early enough to allow effective intervention.
- Role of patient preferences: No role in documenting the outcome, but a significant role in the choice and extent of outcome assessment
- Exclusions: None
- Policy level: Recommendation

Statement 10. Postoperative Laryngeal Examination

Clinicians should examine vocal fold mobility or refer the patient for examination of vocal fold mobility in patients with a change in voice following thyroid surgery (as identified in Statement 9).

Recommendation based on preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C, quality of life (QOL) data, early intervention data, diagnostic maneuver
- Benefit: Detect nerve injury, gain information regarding prognosis, institute rehabilitation as needed
- Risk, harm, cost: Misdiagnosis (false positive/false negative), cost of examination, patient discomfort, resources, access, anxiety, by restricting this recommendation to only patients with a voice change some nerve injuries may be missed
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: The timing of the examination is not specified but should occur expeditiously after the identification of a voice change, as identified in Statement 9.
- Role of patient preferences: Moderate, based on patient self-perception of voice postoperatively, based on type of examination of larynx, based on physician determination and patient consent
- Exclusions: None
- Policy level: Recommendation

Statement 11. Otolaryngology Referral

The clinician should refer a patient to an otolaryngologist when abnormal vocal fold mobility is identified after thyroid surgery.

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C, before and after studies showing voice improvement after surgical intervention
- Benefit: Awareness of the opportunities for early surgical intervention, confirmation of the laryngeal findings, determination of appropriate treatment plan, facilitates shared decision making, facilitates coordination with speech-language pathologist in care of patient
- Risk, harm, cost: Cost, time, access

- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: None
- Policy Level: Recommendation

Statement 12. Voice Rehabilitation

Clinicians should counsel patients with voice change or abnormal vocal fold mobility after thyroid surgery on options for voice rehabilitation.

Recommendation based on systematic reviews and observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade B, systematic reviews on the benefits of counseling in general on health care outcomes; Grade C, observational studies on the effectiveness of interventions for voice rehabilitation
- Benefit: Facilitates informed decision making, reduces anxiety, improves awareness of options for rehabilitation
- Risk, harm, cost: None for counseling; cost for implementation of voice therapy may be significant, depending on patient's insurance status
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Benefits seen in clinical studies from pursuing these options have been extrapolated to a beneficial effect from counseling the patient and increasing awareness
- Intentional vagueness: None
- Role of patient preferences: Substantial regarding the method and extent of counseling provided
- Exclusions: None
- Policy Level: Recommendation

Definitions:

Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong Recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B).* In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C).* In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	An option means that either the quality of evidence that exists is suspect (grade D)* or that well-done studies (grade A, B, or C)* show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
No Recommendation	No recommendation means there is both a lack of pertinent evidence (grade D)* and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

*See the "Rating Scheme for the Strength of Evidence" field for definitions of evidence grades.

Evidence Quality for Grades of Evidence

Grade	Evidence Quality for Diagnostic Tests	Evidence Quality for All Other Studies
A	Systematic review of cross-sectional studies with consistently applied reference standard and blinding	Well-designed randomized controlled trials performed on a population similar to the guideline's target population
B	Individual cross-sectional studies with consistently applied reference standard and blinding	Randomized controlled trials; overwhelmingly consistent evidence from observational studies
C	Nonconsecutive studies, case control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Observational studies (case control and cohort design)
D	Mechanism-based reasoning or case reports	
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm	

Clinical Algorithm(s)

The original guideline document contains a clinical algorithm of the guideline's key action statements.

Scope

Disease/Condition(s)

Neural injury and voice change following thyroid surgery

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Prevention

Rehabilitation

Risk Assessment

Treatment

Clinical Specialty

Endocrinology

Family Practice

Internal Medicine

Oncology

Otolaryngology

Speech-Language Pathology

Surgery

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Speech-Language Pathologists

Guideline Objective(s)

- To provide evidence-based recommendations for management of the patient's voice when undergoing thyroid surgery during the preoperative, intraoperative, and postoperative period
- To optimize voice outcomes for adult patients aged 18 years or older after thyroid surgery
- To define useful actions for clinicians, regardless of discipline, to improve quality of care and voice outcomes

Target Population

Adult patients aged 18 years or older after thyroid surgery

Note: This guideline is *not intended* for the following populations:

Children under age 18 years
Patients undergoing concurrent laryngectomy

Interventions and Practices Considered

Preoperative

1. Baseline voice assessment
2. Preoperative laryngeal assessment of the impaired voice
3. Preoperative laryngeal assessment of the nonimpaired voice
4. Patient education on voice outcomes
5. Communication with anesthesiologist

Intraoperative

1. Identifying recurrent laryngeal nerve
2. Protection of superior laryngeal nerve
3. Intraoperative electromyography (EMG) monitoring
4. Intraoperative corticosteroids (no recommendation made)

Postoperative

1. Postoperative voice assessment
2. Postoperative laryngeal exam
3. Otolaryngology referral
4. Voice rehabilitation

Major Outcomes Considered

- Risk for voice impairment after thyroid surgery
- Validity, sensitivity, specificity, positive and negative predictive value, test efficiency, and diagnostic accuracy and precision of voice assessment methods
- Prevalence and duration of voice changes after surgery
- Rate of return to social, family, and vocational activities
- Effectiveness of voice rehabilitation
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

All literature searches were performed by an information specialist through January 2012. Three initial searches were performed to identify clinical practice guidelines, systematic reviews, and randomized controlled trials (RCTs). The searches were performed in multiple databases including the National Guideline Clearinghouse (NGC), the Cochrane Library, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), EMBASE, PubMed, Web of Science, BIOSIS, the Cochrane Central Register of Controlled Trials (CENTRAL), CMA Infobase, National Health Service (NHS) Evidence ENT and Audiology, National Library of Guidelines, National Institute of Clinical Excellence (NICE), Scottish Intercollegiate Guidelines Network (SIGN), New Zealand Guidelines Group (NZGG), Australian National Health and Medical Research Council (ANHMRC), and the TRIP database.

1. Clinical practice guidelines were identified by a PubMed, NGC, CMA Infobase, NHS Evidence, NZGG, ANHMRC, TRIP database, and the Guidelines International Network (G-I-N) library search using guideline as a publication type or title word. The search identified 7 guidelines after removing duplicates, clearly irrelevant references, and non–English language articles.
2. Systematic reviews were identified through Medline, EMBASE, the Cochrane Library, CINAHL, the Allied and Complementary Medicine Database (AMED), the Agency for Healthcare Research and Quality's (AHRQ), and the TRIP database. The final data set included 50 systematic reviews or meta-analyses that were distributed to the panel members. Articles were excluded if they were not available in English and did not meet the panels' quality criteria, namely, the review had a clear objective and method, an explicit search strategy, and a valid method of data extraction.
3. RCTs were identified through MEDLINE, EMBASE, CINAHL, and CENTRAL and totaled 285 trials.

Results of all literature searches were distributed to guideline panel members including electronic listings with abstracts (if available) of the searches for clinical guidelines, randomized controlled trials, systematic reviews, and other studies. This material was supplemented, as needed, with targeted searches to address specific needs identified in writing the guideline through May 2012.

Number of Source Documents

- 7 guidelines
- 50 systematic reviews or meta-analyses
- 285 randomized controlled trials

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Evidence Quality for Grades of Evidence

Grade	Evidence Quality for Diagnostic Tests	Evidence Quality for All Other Studies
A	Systematic review of cross-sectional studies with consistently applied reference standard and blinding	Well-designed randomized controlled trials performed on a population similar to the guideline's target population
B	Individual cross-sectional studies with consistently applied reference standard and blinding	Randomized controlled trials; overwhelmingly consistent evidence from observational studies
C	Nonconsecutive studies, case control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Observational studies (case control and cohort design)
D	Mechanism-based reasoning or case reports	
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm	

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the quality of evidence and the balance of benefit and harm that is anticipated when the statement is followed. The definitions for evidence-based statements are listed in the "Rating Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations" fields. As much of the guideline dealt with evidence relating to diagnostic tests, the definitions for Evidence Quality for Grades of Evidence (see the "Rating Scheme for the Strength of the Evidence" field) was adapted to include current recommendations from the Oxford Centre for Evidence-Based Medicine.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This guideline was developed using an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm. The guideline development panel was comprised of representatives from the fields of otolaryngology, laryngology, head and neck surgery, nursing, speech-language pathology, endocrinology, internal medicine, general surgery, anesthesiology, and consumer advocacy.

In a series of conference calls, the working group defined the scope and objectives of the proposed guideline. During the 12 months devoted to guideline development, the guideline development group met twice, with in-person meetings following the format previously described, using electronic decision support (BRIDGE-Wiz, Yale Center for Medical Informatics, New Haven, Connecticut) software to facilitate creating actionable recommendations and evidence profiles. Internal electronic review and feedback on each guideline draft was used to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines.

American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) staff used the Guideline Implementability Appraisal and Extractor (GLIA) to appraise adherence of the draft guideline to methodological standards, improve clarity of recommendations, and predict potential obstacles to implementation. Guideline panel members received summary appraisals in May 2012 and modified an advanced draft of the guideline.

Rating Scheme for the Strength of the Recommendations

Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong Recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B).* In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C).* In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	An option means that either the quality of evidence that exists is suspect (grade D)* or that well-done studies (grade A, B, or C)* show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
No Recommendation	No recommendation means there is both a lack of pertinent evidence (grade D)* and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

*See the "Rating Scheme for the Strength of Evidence" field for definitions of evidence grades.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The final guideline draft underwent extensive external peer review. Comments were compiled and reviewed by the panel's chair, and a modified version of the guideline was distributed and approved by the guideline development panel.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

The recommendations contained in the guideline are based on the best available data published through May 2012. Where data were lacking, a combination of clinical experience and expert consensus was used.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate prevention and treatment of neural injury and voice changes after thyroid surgery

For benefits of specific interventions considered in the guideline, see the "Major Recommendations" field.

Potential Harms

- Baseline voice assessment may result in patient anxiety.
- Preoperative laryngeal assessment may result in misdiagnosis (false positive/false negative), patient discomfort, and anxiety.
- Patient education on voice outcomes may result in patient anxiety.
- Identification of the recurrent laryngeal nerve (RLN) during thyroid surgery may result in inadvertent RLN injury, extended operative time, or false identification of another structure as the RLN.
- Protection of the superior laryngeal nerve during thyroid surgery may leave superior pole thyroid tissue.
- Intraoperative electromyography (EMG) during thyroid surgery may result in misinterpretation (both false positive/false negative) and may instill a false sense of security in identifying the nerve.
- Use of intraoperative corticosteroids may result in hyperglycemia.
- Postoperative laryngeal examination may result in misdiagnosis (false positive/false negative), patient discomfort, and anxiety. By restricting this recommendation to only patients with a voice change some nerve injuries may be missed.

Contraindications

Contraindications

The use of long-acting paralytic agents is absolutely contraindicated in neural monitoring cases, and the anesthetic plan must be modified accordingly.

Qualifying Statements

Qualifying Statements

- This guideline is intended to focus on quality improvement opportunities judged most important by the guideline development group (GDG). It is not intended to be a comprehensive guide for managing patients undergoing thyroid surgery. In this context, the purpose is to define useful actions for clinicians, regardless of discipline, to improve quality of care and voice outcomes. Conversely, the statements in this guideline are not intended to limit or restrict care provided by clinicians based on the assessment of individual patients.
- Guidelines are not intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a "strong recommendation" than might be expected with "recommendation." "Options" offer the most opportunity for practice variability. Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations. They must also operate within their scope of practice and according to their training. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.
- This clinical practice guideline is provided for information and educational purposes only. It is not intended as a sole source of guidance in

managing voice outcomes after thyroid surgery. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions, but they are not absolute. Guidelines are not mandates and do not and should not purport to be a legal standard of care. The responsible physician, in lights of all the circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), Inc. emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care, or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

Implementation of the Guideline

Description of Implementation Strategy

Implementation Considerations

The clinical practice guideline is published as a supplement to *Otolaryngology–Head and Neck Surgery*, which will facilitate reference and distribution. A full-text version of the guideline will be accessible, free of charge, at http://www.entnet.org. In addition, all the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) guidelines are now available via the *Otolaryngology–Head and Neck Surgery* app for smartphones and tablets. The guideline will be presented to American Academy of Otolaryngology-Head and Neck Surgery members as a miniseminar at the AAO-HNSF Annual Meeting & OTO EXPO. Existing brochures and publication by the AAO-HNSF will be updated to reflect the guideline's recommendations.

As a supplement to clinicians, an algorithm of the guideline's action statements has been provided (see Figure 5 in the original guideline document). The algorithm allows for a more rapid understanding of the guideline's logic and the sequence of the action statements. The guideline development group hopes the algorithm can be adopted as a quick reference guide to support the implementation of the guideline's recommendations.

To support clinicians' adoption of Key Action Statement 3 (see the "Major Recommendations" field), patient education of voice outcomes, a set of discussion points has been developed (see Table 7 in the original guideline document). The table highlights key points to be discussed with the patient both pre- and postoperatively. Specifically, the surgeon should discuss possible surgical risks and their relation to voice outcomes and any potential benefits. The guideline development group (GDG) recommends these materials can be incorporated into future educational materials.

To assist readers of the guideline who may be unfamiliar with the anatomy of the thyroid, several diagrams have been provided in the original guideline document. The diagrams identify the location of the thyroid gland and the position of both the superior laryngeal nerve (SLN) and the recurrent laryngeal nerves (RLN).

Implementation Tools

Clinical Algorithm

Quick Reference Guides/Physician Guides

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Chandrasekhar SS, Randolph GW, Seidman MD, Rosenfeld RM, Angelos P, Barkmeier-Kraemer J, Benninger MS, Blumin JH, Dennis G, Hanks J, Haymart MR, Kloos RT, Seals B, Schreibstein JM, Thomas MA, Waddington C, Warren B, Robertson PJ. Clinical practice guideline: improving voice outcomes after thyroid surgery. Otolaryngol Head Neck Surg. 2013 Jun;148(6 Suppl):S1-37. [256 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Jun

Guideline Developer(s)

American Academy of Otolaryngology - Head and Neck Surgery Foundation - Medical Specialty Society

Source(s) of Funding

American Academy of Otolaryngology–Head and Neck Surgery Foundation

Guideline Committee

American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) Foundation Guideline Development Panel

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Financial Disclosure and Conflicts of Interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF). Potential conflicts of interest for all panel members in the past 5 years were compiled and distributed before the first conference call. After review and discussion of these disclosures, the panel concluded that individuals with potential conflicts could remain on the panel if they: (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Lastly, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.

Disclosures

Competing interests: Sujana S. Chandrasekhar, Scientific Development & Research Inc.—shareholder, board member, CMO, Med El Corporation—grant recipient; Michael D. Seidman, Body Language vitamins (founder), Visalus Sciences (director of product development), National Institutes of Health (NIH) (grant recipient), *Save Your Hearing Now* (author, no royalties); Peter Angelos, Olympus—consultant; Gregory Dennis, UCB Inc—employer, Human Genome Sciences—previous employer; Richard T. Kloos, Bayer, Eisai, Onyx, Exelixis—research investigator, Veracyte—stockholder and employee, Thompson Hine LLP—expert witness, Genzyme Corporation—consultant; Jerry M. Schreibstein, Sleep Management Solutions—medical director, Pioneer Valley Surgicenter—owner.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the American Academy of Otolaryngology-Head and Neck Surgery Web site .

Availability of Companion Documents

The following are available:

- Clinical practice guideline: improving voice outcomes after thyroid surgery (a summary). Bulletin. 2013 Jun;32(06):various p. Electronic copies: Available from the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) Bulletin Web site .
- Clinical practice guideline: improving voice outcomes after thyroid surgery. Podcast Part 1 and 2. Alexandria (VA): American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNS). 2013 Jun. Available from the SAGE Journals Online Web site .
- Research gaps - improving voice outcomes after thyroid surgery. Alexandria (VA): American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNS). 2013 Jun. Electronic copies: Available from the AAO-HNSF Web site .
- Clinical practice guideline: improving voice outcomes after thyroid surgery. Fact sheet. Alexandria (VA): American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNS). 2013 Jun. 2 p. Electronic copies: Available in Portable Document Format (PDF) from the AAO-HNSF Web site .
- Rosenfeld RM, Shiffman RN, Robertson P. Clinical practice guideline development manual, third edition: a quality-driven approach for

translating evidence into action. Otolaryngol Head Neck Surg. 2013;148(Suppl 1):S1-55. Electronic copies: Available from the SAGE Journals Online Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on September 9, 2013. The information was verified by the guideline developer on October 9, 2013. This summary was updated by ECRI Institute on February 15, 2017 following the U.S. Food and Drug Administration advisory on general anesthetic and sedation drugs.

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